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10/510,917	10/12/2004	Yoshinori Amano	28951.5346	4324

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STEPTOE & JOHNSON LLP  
1330 CONNECTICUT AVE., NW  
WASHINGTON, DC 20036

EXAMINER
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WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1797

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03/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,917	<b>Applicant(s)</b> AMANO ET AL.	
	<b>Examiner</b> P. Kathryn Wright	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2004</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, drawn to a biosensor cartridge; and

Group II, claim(s) 24-50, drawn to a biosensor dispensing device.

2. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-II do not relate to a single inventive concept because they lack the same or corresponding special technical feature for the following reasons.

The technical feature linking Groups I-II relates to a biosensor cartridge having a sensor send-out means for ejecting individual biosensors stacked in a case through a send out port opened in the case. However, as discussed further below, Pugh (US Patent. Pub. 2003/0116583) teaches cartridge 84 for storing a plurality of biosensors 62 in a case 86 in a stacked manner. The Pugh cartridge storing chamber 36 also includes sensor send-out means 47 for sending out the biosensor in the case 86 one by one and discharging the biosensor from a sensor ejecting port 92 opened at the case (see paragraph [0042] and Figs. 2b and 4).

Therefore, the technical features linking the invention of Groups I-II do not constitute a special technical feature as defined by PCT 13.2, as it does not define a contribution over the prior art.

In addition, Group II has technical features that are unrelated to Group I. In particular, Group II includes the feature of an operating part for turning the sensor sending out mechanism ON and OFF outside the body in an exposed manner, which is not required limitation of Group I.

Accordingly, Groups I-II are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

3. During a telephone conversation with Roger Parkhurst on March 19, 2008 a provisional election was made with traverse to prosecute the invention of Group II, claims 24-50. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

5. Figures 19A-20B should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

7. The abstract of the disclosure is objected to because it contains legal phraseology often used in patent claims, such as "means" and "said," which should be avoided. Correction is required. See MPEP § 608.01(b).

8. The specification is objected to because it fails to provide a description of Figs. 14A-B, 16A-B, 17A-B in the BREIF DESCRIPTION OF THE DRAWING section, see pages 18-19.

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 24-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 penultimate paragraph, recites “a sensor conveying mechanism...inside a body...” It is not clear what “body” Applicant is referring to. Furthermore, the body has not been positively recited in the claim. The claim is incomplete since it omits essential structural cooperative relationships of elements, amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are between the “body” and the other elements of the claim (e.g., cartridge, sensor sending out mechanism, sensor conveying mechanism and operating part, etc). Same deficiency was found in claims 25-28, 34, 36, 44, and 45.

Claims 24, 25 and 41 recite “means for sending”, “means for pressing”, and means for connecting or releasing connection”, respectively. The Examiner has interpreted these limitations as a means-plus-function limitation covered by 35 USC 112, sixth paragraph. This interpretation is proper since the claim limitation recites “means for” language, and the “means for” is not modified by sufficient structure for achieving the specified function. A means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function. For claims falling under 35 USC 112, sixth paragraph, Examiners are required to construe claims as covering the corresponding structure, material, or acts described in the specification and equivalents thereof, see *In re Donaldson Co.*, 29 USPQ2d 1845 (Fed. Cir. 1994). However, the specification does not set forth the corresponding structure. Thus, it is unclear and indefinite what structures Applicant is intending to encompass with the “means for” limitations.

For purposes of examination, the Examiner has strictly construed the “means for sending” limitation as the “pushing member 31”, since the specification does support the use of a pushing member for pushing the biosensor towards the biosensor ejection port, see page 21, lines 11-15. Additionally, the “means for pressing” limitation has strictly construed as the “electrode arm 48”, since the specification does support the use of an electrode arm for pressing and holding the biosensor conveyed to the test position and conducting the biosensor to an electrical circuit, see page 26, lines 4-8. The structure that corresponds to “means for connecting or releasing connection” cannot be located in the specification by the Examiner. Clarification is required.

Since Applicant fails to set forth an adequate disclosure, applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.

Claim 27 recites "a cartridge storing chamber including a cylindrical rotating member and a sliding member sliding with the rotation of the rotating member to push the rear end of the biosensor as sensor send-out means,..." Claim 46 recites a sliding member for pushing the rear end of the biosensor as the sensor send-out means,..." These appear to be an incomplete statements. It is not clear what the sensor send-out means is intended to do in either claim.

Claim 33 recites "wherein each link member supporting the sensor conducting means and the valve means". These link members lack antecedent basis since no link members have been recited as supporting the sensor conducting means and the valve means.

Claim 40 recites "the detection means recognizes a contact with a member configuring one part of the operating part". It is not clear what member is Applicant referring to. The member configuring one part of the operating part cannot be located in the specification, thus, the scope of the claim cannot be determined.

Claim 42 recites, *inter alia*, the operation of *the operating part is stopped is arranged on the sliding path*. It is not clear what Applicant is trying to recite.

Clarification is required.



***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 26-41, and 44-50 as best understood, are rejected under 35

U.S.C. 102(e) as being anticipated by Pugh (US Patent. Pub. 2003/0116583).

Pugh teaches a biosensor dispensing device comprising a cartridge storing chamber (area inside housing including chamber 36) detachably holding a biosensor cartridge 84 for storing a plurality of biosensors 62 in a case 86 in a stacked manner. The cartridge storing chamber 36 also includes sensor send-out means 47 for sending out the biosensor in the case 86 one by one and discharging the biosensor from a sensor ejecting port 92 opened at the case (see paragraph [0042] and Figs. 2b and 4) and a sensor sending out mechanism 51 for driving the sensor send-out means in the biosensor cartridge (see paragraph 0035] and Fig. 3) .

The Pugh dispensing device also includes a sensor conveying mechanism (i.e., pushing member 116) for conveying the biosensor discharged from the sensor ejecting port 92 by the sensor send-out means to a predetermined test position at where a sample can be applied and an operating part 71 for turning the sensor sending out

mechanism ON and OFF (see for example embodiments of sensor conveying mechanism shown in Figs. 6, 8-25b).

With respect to claim 25 Pugh dispenser also includes a sensor conducting means for pressing and holding (electrodes 122) the biosensor conveyed to the test position and conducting the biosensor to an electrical circuit within the body (see paragraph [0050]).

Regarding claims 26 and 49, the biosensor dispensing device of Pugh includes a display unit (not shown) provided on an exterior surface of the body in order for acquiring electrical data from the biosensor conveyed to the test position through the electrical circuit within the body, and displaying data (see paragraphs [0049] and [0056], see Figs. 4, 5 and 13).

As to claim 27, as best understood, the Pugh cartridge storing chamber includes a cylindrical rotating member (reads on gear member 136) and a sliding member 73 sliding with the rotation of the rotating member is 136 configured to push the rear end of the biosensor (see embodiments of Figs. 16-20). The operating part 71 is configured so as to move (slide) the sensor sending out mechanism 116 with a forefinger while gripping the body with one hand (see paragraph [0032]).

Regarding claim 28, the operating part 71 freely exits (extends) from the device and operates the sensor sending out mechanism.

With respect to claim 29, the sensor sending out mechanism drives the sensor send-out means 51 to discharge the biosensor in a direction opposite (upwardly) the direction of pushing in the operating part (down and to the laterally).

As to claim 30, the Pugh dispensing device further comprises a valve means (reads on sealing member 97) which opens and closes the sensor ejecting port 92 opened at the case of the biosensor cartridge (see paragraph [0035]). The up/down movement of the biosensor cartridges causes the sealing member 97 to act as a "roller" which seals the exterior surface of the sensor ejecting port 92.

With respect to claim 32, the sensor conducting means (electrodes 122) and the valve means 97 are gear-coupled via gear segments 113, 114 to the sensor sending out mechanism (see for example paragraph [0047] and Figs. 16-17).

Regarding claim 33, a link member supports the sensor conducting means 122 and the valve means 97, and a cam 74 holds each link member onto the operating part 71 (see for example Figs. 6-7).

Claims 34 and 36 are directed to the manner in which the dispensing device is operated. These limitations do not impart patentability to the claims because they are directed to how the device functions; whereas, patentability in an apparatus claim is determined by the structure of the device.

As to claim 35, Pugh teaches a power source (means for powering), (see paragraph [0049]).

Regarding claims 37-38, The Pugh device includes a cartridge holding mechanism 113, 114 for unremovably holding the biosensor cartridge during the operation of the operating part. The cartridge holding mechanism is gear- coupled to the operating part 71 (see Figs. 16-17).

With respect to claims 39-40 and 48, the dispensing device of Pugh further comprising detection means (includes electrodes 122) capable detecting the return of the operating part to the initial position (paragraphs 0054]-[0057])).

As to claim 41, dispenser mechanism of Pugh includes a connection switching means for connecting or releasing connection with respect to the sensor send-out means of the biosensor cartridge in cooperation with the opening/closing operation of a lid body 41 that opens/closes the cartridge storing chamber when attaching/detaching the biosensor cartridge.

Regarding claims 44-45, the gears in the embodiment shown in Figs. 25-25d of Pugh can act as a latch mechanism (i.e., latch projections) for locking the operating part 71 at a position at where the biosensor is set to the test state with respect to the body.

Regarding claim 46, the cartridge storing chamber includes a sliding member 102 for pushing the rear end of the biosensor (see Fig. 4). The sensor sending out mechanism includes a pushing member 116 for pushing and sliding the sliding member of the biosensor cartridge. The operating part is configured so as to electrically operate the sensor sending out mechanism.

As to claim 47, the Pugh biosensor cartridge includes a seal plate (same as valve means 97) for opening the sensor ejecting port only when discharging the biosensor.

Regarding claim 50, the sensor sending out mechanism 47 and the sensor conveying mechanism 116 of Pugh are independently operable.

***Allowable Subject Matter***

14. Claims 42-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter. As discussed above, Pugh does teach a biosensor dispensing device comprising a cartridge storing chamber detachably holding a biosensor cartridge for storing a plurality of biosensors in a case in a stacked manner and including sensor send-out means for sending out the biosensor in the case one by one and discharging the biosensor from a sensor ejecting port opened at the case. The Pugh device includes a sensor sending out mechanism for driving the sensor send- out means in the biosensor cartridge, wherein the cartridge storing chamber can hold the biosensor cartridge including a cylindrical rotating member and a sliding member sliding with the rotation of the rotating member to push the rear end of the biosensor as sensor send-out means; the sensor sending out mechanism includes a rotating means for rotating the rotating member of the biosensor cartridge, and the operating part is configured so as to move the sensor sending out mechanism with a forefinger while gripping the body with one hand.

However none of the known prior art, including Pugh, teaches or suggests a nail member provided on the operating part in an oscillating manner, a sliding path on which a distal end of the nail member slides is formed in an inner wall of the body, and a saw-

blade concavo-convex part for locking the distal end of the nail member and positionally fixing the operating part when the operation of the operating part is arranged on the sliding path.

### ***Conclusion***

16. No claims are allowed.
17. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure as general background information related to Applicant's field of endeavor.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1797

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pkw

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797